PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SJ20015PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/00635	International filing date *(day/month/year)* 12 January 2004 (12.01.2004)	Priority date *(day/month/year)* 20 January 2003 (20.01.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 39/12; C12Q 1/70 and US Cl.: 424/211.1; 435/5		
Applicant ST. JUDE CHILDREN'S RESEARCH HOSPITAL		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      ____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I — Basis of the report
   - ☐ Box No. II — Priority
   - ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV — Lack of unity of invention
   - ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI — Certain documents cited
   - ☐ Box No. VII — Certain defects in the international application
   - ☐ Box No. VIII — Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14 August 2004 (14.08.2004)	14 March 2005 (14.03.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Stacy B. Chen Telephone No. 703-308-0196

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/00635

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____ , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-24 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 25 and 26 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages_____

☐ the claims, Nos._____

☐ the drawings, sheets/figs_____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*):_____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages_____

☐ the claims, Nos._____

☐ the drawings, sheets/figs_____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*):_____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/00635

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 6-16	YES
	Claims 1-5	NO
Inventive Step (IS)	Claims 6-16	YES
	Claims 1-5	NO
Industrial Applicability (IA)	Claims 1-16	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-5 lack novelty and inventive step under PCT Article 33(2) and (3), respectively, as being anticipated by Wang *et al.* (*J. Virol.* May 1994, 68(5):3369-3373, herein, "Wang"). The claims are drawn to an immunogenic composition for protecting humans against human parainfluenza virus (HPIV) infection comprising a Sendai virus and a pharmaceutically acceptable carrier. The Sendai virus is administered in the amount of between $1x10^5$ to $1x10^8$ plaque forming units (pfu). The composition is formulated for administration to the upper respiratory tract or topical application, and can be in the form of a spray, droplet(s) or aerosol. Wang discloses a mutant vaccine derived from a strain of Sendai virus that is administered to mice intranasally in the amount of $2.5x10^5$ cell infecting units (abstract and page 3370-3371, bridging paragraph). Intranasal administration is a form of topical administration because the composition directly contacts a surface (nasal passage). Therefore, the claims are anticipated by Wang.

Claims 6-16 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for protecting a human against HPIV infection comprising administering a Sendai virus composition.

Claims 1-16 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in the biotechnology industry.

On 29 October 2004, Applicant responded to the First Written Opinion that was mailed 22 September 2004. Applicant's remarks have been carefully considered. First, Applicant asserts that the vaccine suggested by Wang is a mutant form of Sendai virus, while the claims are drawn to unmodified Sendai virus. In response, the claims do not specify that the virus is unmodified. Applicant is arguing a limitation that is not present in the claims. Second, Applicant asserts that the vaccine suggested by Wang is for mice, not humans, and as claims 1-5 are meant for humans, Wang does not anticipate the claims. In response, the actual content of the claims is a Sendai virus and a pharmaceutically acceptable carrier. Applicant is arguing that the intended use of the composition (protecting humans) disqualifies Wang as prior art. However, the composition itself is anticipated by Wang. Lastly, Applicant argues that the vaccine composition described by Wang is intended to protect against Sendai virus, while the instant claims are directed to protecting against human parainfluenza virus. In response, Applicant is arguing that the intended use of the composition disqualifies Wang as prior art. However, the composition itself is anticipated by Wang. Intended uses of compositions do not render the compositions themselves novel or unobvious. Therefore, Wang anticipates and renders obvious the claimed invention of claims 1-5.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: